

### **INTERVIEW SUMMARY**

A telephonic interview was conducted on July 26, 2006. Applicants thank the Examiner for the courtesy of granting the interview. Participating in the interview were Examiner Schnizer, Applicants' Attorney Burns, and Applicants Drs. Luz Montesclaros and Larry Greenfield. The pending claim rejections and the cited references were discussed, particularly the alleged teachings of the Kuipers et al. reference Ann. Rheum. Dis. 1999; 58:103-108 ("Kuipers I"), in light of the pending claims. The Examiner agreed to reconsider the art rejections.

### **REMARKS**

Claims 1-18, 20-21, and 23-33 are currently pending; claims 19 and 22 have been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of these canceled claims at a later date. Claim 14 has been amended to more clearly describe the present invention. Claim 21 has been amended to incorporate the claim limitation of cancelled Claim 22. Claim 23 has been amended so that it now depends on Claim 21. Support for these amendments are found throughout the specification and the originally filed claims, for example but not limited to, paragraphs [0007], [0043], [0044], and [0045] and original claim 22.

#### **Rejections Under 35 U.S. C. §102**

Claims 14-17 have been rejected under 35 USC § 102(e) as allegedly being anticipated by Domanico et al. (US Published Application 20040180445; "Domanico"). See Office Action at pages 3-4. Applicants respectfully disagree

and traverse this rejection. However, solely to expedite prosecution and in no way acquiescing to the Examiner's assertions, claim 14 has been amended to recite that the combination comprises at least one protease. Claims 15-17 are dependent, directly or indirectly, on Claim 14. Thus, Applicants respectfully assert that this amendment renders the rejection moot.

Rejections Under 35 U.S.C. §103

Claims 1-18 and 20-24.

Claims 1-18 and 20-24 are rejected as being unpatentable over Kuipers I in view of Domanico since allegedly it would have been obvious to use a zwitterionic detergent in the putative method of Kuipers I. See Office Action at pages 4-6. The Examiner contends that Kuipers I teaches a method of isolating Chlamydia genomic DNA by treating synovial fluid with proteinase K and either an ionic or a nonionic detergent, addition of CTAB, addition of a solid support, and elution of the DNA from the support. See Office Action at page 4. The examiner specifically cites methods 3b, 3c, 4b and 4c and the text describing those four methods as the basis for this assertion. *Id.*

The Examiner concedes that Kuipers I does not disclose a zwitterionic detergent or a chaotrope. To overcome these deficiencies, the Examiner alleges, inter alia, that Domanico taught the use of zwitterionic detergents and chaotropes in a lysis buffers for DNA isolation procedures. The Examiner therefore concludes that it would have been obvious to use a zwitterionic detergent in the putative method of Kuipers I because, the Examiner asserts, Domanico taught that zwitterionic detergents could be used in DNA isolation

procedures. See Office Action at pages 4-5. Applicants respectfully disagree and traverse this rejection.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2142.

Applicants note that each of the four methods of Kuipers I cited by the Examiner comprise an organic extraction step and neither method 3b nor 3c include the addition of a solid support or the elution of DNA from that support. The current claim language of Claim 1 recites forming a combination comprising at least one protease, at least one zwitterionic detergent and the sample and "exposing the *combination* to at least one solid phase ...". See Claim 1 (emphasis added). Applicants respectfully assert that the methods of Kuipers I does not teach or suggest this limitation of Claim 1. Methods claims 2-18 and 20 depend either directly or indirectly on Claim 1. Applicants also respectfully assert that this deficiency of Kuipers I is not overcome when combined with Domanico. Applicants assert that the Office has not established a prima facie case of obviousness. Thus, withdrawal of the rejection is respectfully requested.

With respect to kit claims 21 and 25-31, the Examiner asserts that it would have been obvious to create a kit comprising the elements Kuipers I, as modified by Domanico. See Office Action at page 6. Applicants respectfully traverse this rejection.

None of pending Claims 21 and 25-31 include phenol/chloroform, ethanol, or chloroform, in contrast to the alleged teachings of Methods 3b, 3c, 4b, and 4c of Kuipers I, cited by the Examiner. See Office Action at page 4. Applicants respectfully assert that the person of skill in the art would not be motivated to combine the components of the cited methods of Kuipers I, including organic one or more organic solvents, even as modified by Domanico, to obtain the Applicants kits. Further, other than an unsubstantiated assertion, the Examiner has provided no evidence that the person of ordinary skill would be motivated to assemble a kit comprising the experimental reagents of Kuipers I and/or Domanico. For at least these reasons, Applicants believe that this rejection is improper and request that the Examiner withdraw the rejection

Claims 21 and 25-31

Claims 21 and 25-31 are rejected as allegedly being unpatentable over Domanico. See Office Action at pages 6-7. The Examiner contends that Domanico taught a method for isolating nucleic acid using a lysis solution comprising guanidine hydrochloride, guanidine thiocyanate, N-decyl-N,N-dimethyl-3-ammonio-1-propanesulfonate and binding the nucleic acid to a solid matrix. See Office Action at page 6. The kit of claim 21 comprises at least one protease. Applicants respectfully assert that Domanico neither teaches or

suggests the use of one or more protease in the lysis solution, thus the kit of Claim 21 is not rendered obvious by the alleged teachings of Domanico . Claims 25-31 depend on claim 21, either directly or indirectly. In light of the foregoing, reconsideration and withdrawal of the rejection is respectfully requested.

#### Claims 32 and 33

Claims 32 and 33 are alleged unpatentable over Kuipers I and Domanico, as the Examiner has applied these two references to Claims 1-18 and 20-24. The Examiner further relies on Kuipers et al. (Arthritis and Rheumatism (1998 Oct) Vol. 41, No. 10, pp. 1894-5) ("Kuipers II") because, the Examiner asserts, Kuipers II taught detecting Chlamydia gDNA from peripheral blood leukocytes. Applicants respectfully traverse this rejection.

As noted above, the combination of Kuipers I and Domanico does not teach or suggest "exposing the combination" to at least one solid phase. Rather, the alleged methods of Kuipers I cited by the Examiner each comprise an intermediate organic extraction step. This deficiency is not overcome by Kuipers II. Applicants respectfully request that this rejection be reconsidered and withdrawn.

#### Obviousness-type Double Patenting Rejections

Claims 1-3, 5-12, 14, 15, 17-19, and 21-30 are rejected as allegedly being unpatentable over claims 1-64 of U.S. Patent No. 6,762,027 (the '027 patent). Applicants respectfully request that this rejection be held in abeyance until patentable subject matter has been identified.

**CONCLUSION**

Applicants believe that the application is now in condition for allowance and respectfully request issuance of a Notice of Allowance. If the Examiner does not consider the application to be in condition for allowance, Applicants request that he call the undersigned at (760) 931-6676 to set up an interview.

**PETITION FOR EXTENSION OF TIME AND FEE AUTHORIZATION**

A petition for a Three Month Extension of Time is being transmitted concurrently. Should any extension of time and/or fee be necessary for timely submission of this paper, such extension of time is hereby requested. The Commissioner is authorized to charge **Deposit Account No. 01-2213 (5063)**. Any deficiency or overpayment should be charged or credited to this deposit account.

Respectfully submitted,

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